

Translation

PATENT COOPERATION TREATY PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 0000054442	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/EP2004/003628	International filing date (<i>day/month/year</i>) 06.04.2004	Priority date (<i>day/month/year</i>) 08.04.2003
International Patent Classification (IPC) or national classification and IPC		
Applicant BASF PLANT SCIENCE GMBH		

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 8 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (<i>sent to the applicant and to the International Bureau</i>) a total of _____ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>																	
<p>4. This report contains indications relating to the following items:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%;"><input checked="" type="checkbox"/></td> <td style="width: 85%;">Box No. I Basis of the report</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. II Priority</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. IV Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VI Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VII Certain defects in the international application</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VIII Certain observations on the international application</td> </tr> </table>		<input checked="" type="checkbox"/>	Box No. I Basis of the report	<input checked="" type="checkbox"/>	Box No. II Priority	<input type="checkbox"/>	Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI Certain documents cited	<input type="checkbox"/>	Box No. VII Certain defects in the international application	<input type="checkbox"/>	Box No. VIII Certain observations on the international application
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Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

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Box No. I

Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:
- international search (Rule 12.3 and 23.1(b))
 - publication of the international application (Rule 12.4)
 - international preliminary examination (Rule 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

- the international application as originally filed/furnished
 the description:
 pages 1-35 as originally filed/furnished
 pages* _____ received by this Authority on _____
 pages* _____ received by this Authority on _____
 the claims:
 nos. 1-19 as originally filed/furnished
 nos.* _____ as amended (together with any statement) under Article 19
 nos.* _____ received by this Authority on _____
 nos.* _____ received by this Authority on _____

- the drawings:
 sheets 1/8-8/8 as originally filed/furnished
 sheets* _____ received by this Authority on _____
 sheets* _____ received by this Authority on _____
 a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. The amendments have resulted in the cancellation of:

- the description, pages _____
- the claims, nos. _____
- the drawings, sheets/figs _____
- the sequence listing (*specify*): _____
- any table(s) related to sequence listing (*specify*): _____

4. This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- the description, pages _____
- the claims, nos. _____
- the drawings, sheets/figs _____
- the sequence listing (*specify*): _____
- any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. II Priority

1. This report has been established as if no priority had been claimed due to the failure to furnish within the prescribed time limit the requested:
 - copy of the earlier application whose priority has been claimed (Rule 66.7(a)).
 - translation of the earlier application whose priority has been claimed (Rule 66.7(b)).
2. This report has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rule 64.1). Thus for the purposes of this report, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

Document MEYER ET AL: "Biosynthesis of docosahexaenoic acid in *Euglena gracilis*: Biochemical and molecular evidence for the involvement of a Δ4-fatty acyl group desaturase", BIOCHEMISTRY, Vol. 42, No. 32, 19 August 2003, pages 9779-9788, was cited in the search report as a P document.

Since a copy of the priority document is not yet available, it is not possible to recognise whether that document is part of the prior art. Consequently, that document is not taken into account for substantiating this report.

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International application No.

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	
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1. Statement

Novelty (N)	Claims	YES
	Claims <u>1-19</u>	NO
Inventive step (IS)	Claims	YES
	Claims <u>1-19</u>	NO
Industrial applicability (IA)	Claims <u>1-19</u>	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

1. The present application relates to an enzyme from *Euglena gracilis* with Δ4-desaturase activity.
2. This report makes reference to the following documents:

D1: WO 02/090493 A (ABBOTT LAB) 14 November 2002

D2: WO 02/26946 A (BIORIGINAL FOOD & SCIENCE CORP) 4 April 2002

D3: PEREIRA SUZETTE L ET AL: "Recent advances in the study of fatty acid desaturases from animals and lower eukaryotes." PROSTAGLANDINS LEUKOTRIENES AND ESSENTIAL FATTY ACIDS, Vol. 68, No. 2, February 2003, pages 97-106

D4: BARSANTI LAURA ET AL: "Fatty acid content in wild type and WZSL mutant of *Euglena gracilis*: Effects of carbon source and growth conditions" JOURNAL OF APPLIED PHYCOLOGY, Vol. 12, No. 3-5, October 2000, pages 515-520

D5: LOPEZ ALONSO D ET AL: "Plants as 'chemical factories' for the production of polyunsaturated fatty acids" BIOTECHNOLOGY ADVANCES, Vol. 18, No. 6, October 2000, pages 481-497

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
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D6: WALLIS J G ET AL: "The Δ 8-desaturase of *Euglena gracilis*: An alternate pathway for synthesis of 20-carbon polyunsaturated fatty acids" ARCHIVES OF BIOCHEMISTRY AND BIOPHYSICS, Vol. 365, No. 2, 15 May 1999, pages 307-316

3. Novelty

3.1 The present application does not meet the requirements of PCT Article 33(1) because the subject matter of **claims 1-19** is not novel (PCT Article 33(2)).

3.2 **Claim 1** relates to nucleic acid sequences with at least 40% homology on the amino acid level with SEQ. ID. No. 2 and Δ 4-desaturase activity.

D1 discloses an enzyme from *Thraustochytrium* species with Δ 4-desaturase activity and 40.36% identity with SEQ. ID. No. 2.

D2 discloses an enzyme from *S. aggregatum* with Δ 4-desaturase activity and 43.51% identity with SEQ. ID. No. 2.

D1 and **D2** also disclose vectors, cells, transgenic organisms and plants which contain these nucleic acid sequences, processes for producing unsaturated fatty acids using these enzymes, and oils, fatty acids and compositions produced by using these enzymes.

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Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

For this reason, the subject matter of **claims 1-19** does not meet the requirements of PCT Article 33(2).

4. Inventive step

4.1 The present application does not meet the requirements of PCT Article 33(1) because the subject matter of **claims 1-19** does not involve an inventive step (PCT Article 33(3)).

4.2 **Claim 1** relates to a nucleic acid sequence with the sequence represented by SEQ. ID. No. 1, or nucleic acid sequences which code for the amino acid sequence represented by SEQ. ID. No. 2.

It is known from **D4** and **D6** that *Euglena gracilis* produces DHA (docosahexanoic acid). It is known from **D5** that microalgae, unlike higher eukaryotes, produce Δ4-desaturase, which is required for the production of DHA. Consequently, *Euglena gracilis* must show Δ4-desaturase activity, i.e. produce a Δ4-desaturase enzyme.

D3 explicitly discloses the need to isolate new desaturases for the production of new oils and fatty acids.

In view of documents **D3-D6**, a person skilled in the art would use similar methods as in **D1** or **D2**

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in order to isolate the Δ4-desaturase enzyme from *Euglena gracilis* or the nucleic acid sequence that codes therefor. This can be achieved with a high expectation of success and without an inventive step.

For this reason, the subject matter of claims 1-19 does not meet the requirements of PCT Article 33(3).

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Supplemental Box Relating to Sequence Listing

Continuation of Box No. 1, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis of:
 - a. type of material
 - a sequence listing
 - table(s) related to the sequence listing
 - b. format of material
 - in written format
 - in computer readable form
 - c. time of filing/furnishing
 - contained in the international application as filed
 - filed together with the international application in computer readable form
 - furnished subsequently to this Authority for the purposes of search and/or examination
 - received by this Authority as an amendment* on _____
2. In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional comments:

The sequence listing in the description, pages 1-6 as originally filed.

If item 4 in Box No. 1 applies, the listing and/or table(s) related thereto, which form part of the basis of the report, may be marked "superseded."